DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2015

Medyssey USA, Incorporated
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K142835
Trade/Device Name: Iliad Pedicle Screw System and Zenius Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: May 12, 2015
Received: May 14, 2015

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142835

Device Name
Iliad Pedicle Screw System and Zenius Pedicle Screw System

Indications for Use *(Describe)*
The Medyssey Co, Ltd. Iliad Pedicle Screw System and Zenius Pedicle Screw System are intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation): spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:	June 11, 2015
Submitter:	John Kuczynski, VP R&D and RA Medyssey USA Inc. 1550 E. Higgins Road Suite 123 Skokie, IL 60077 847-427-0200 888-518-9070 (fax)
Regulatory Contact:	Rich Jansen, Pharm. D. Silver Pine Consulting
Product	
Trade Names:	Iliad Pedicle Screw System and Zenius Pedicle Screw System
Product Class:	Class III
Classification:	21 CFR §888.3070 Pedicle Screw Spinal System; and 888.3050 – Spinal Interlaminal fixation orthosis
Common Name:	Pedicle Screw System
Product Codes:	NKB, MNI, MNH, KWP
Panel Code:	87

Purpose:

The purpose of this Premarket Notification is to add components and addition to the previously cleared Iliad and Zenius pedicle screw systems to better facilitate use in deformity surgeries.

Device Descriptions:

The **Iliad™** Spinal Fixation and Adjustable Bridge System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients.
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136. The Cobalt-Chrome rods are made from wrought Co-Cr-Mo alloy, which complies with ASTM F1537.

The **Zenius™** Spinal System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients. Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136. The Cobalt-Chrome rods are made from wrought Co-Cr-Mo alloy, which complies with ASTM F1537.

Indications for Use:
The Medyssey Co, Ltd. Iliad Pedicle Screw System and Zenius Pedicle Screw System are intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation): spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Predicate Device(s):
Medyssey believes these devices are substantially equivalent to predicate devices previously cleared by FDA. The CD Horizon system by Medtronic (K042025) is the primary predicate.
Additional predicate devices include the Iliad and Zenius systems (K131878), the Expedium Spine System by DePuy Spine (K102249), the Optima system by U&I (Zimmer) (K051971), and the Xia system by Stryker (K001272).

Technological Characteristics:
The Iliad and Zenius Pedicle Screw Systems share the same indications for use, design, material, performance, and fundamental technologies as the predicate devices.

Performance Standards:
The pre-clinical testing was performed by an independent laboratory. Testing was conducted per ASTM F1717-13 and ASTM F1798-13. Testing included:

- Flexural Grip
- Torsional Grip
- Static Compression Bending
- Dynamic Compression Bending

Conclusion:
Medyssey concludes that the additions to the previously cleared Iliad and Zenius pedicle systems raise no new questions of safety or effectiveness and are substantially equivalent to the predicate devices.